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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/775,750 02/02/01 JONGSMA

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HM12/0418

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EXAMINER

FOLEY, S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED:

04/18/01

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/775,750	JONGSMA ET AL.
	Examiner	Art Unit
	Shanon A. Foley	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|--|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-16 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-16 of copending Application No. 09/515732. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17 and 18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6, 10, 15, and 16 of copending Application No. 09/515732. Although the conflicting claims are not identical, they are not patentably distinct from each other because the immunogenically-effective amount of the

vaccine administered is identical in amount and content to the process of protecting chickens in claims 1-6 of 09/515732. Although the composition or process claims of 09/515732 do not specify that the composition contains no virus neutralizing factor, it would be apparent that the composition would have to remain virulent enough to induce a protective effect in chickens that are maternal-antibody-positive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for use in birds, does not reasonably provide enablement for any host animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to a process for protecting host animals by administering a composition *in ovo* to a host animal. The invention is directed to protecting chickens against infectious bronchitis virus. There is no direction, guidance, or working example provided in the specification drawn to administering the vaccine *in ovo* to mammals, fishes, reptiles, ect. One skilled in the art would not be able to predict the effect or reasonably discern how to administer infectious bronchitis virus during incubation *in ovo* to mammals, fishes, reptiles, ect, without a

Art Unit: 1648

significant amount of guidance. Therefore, it is determined that an unreasonable amount of experimentation would be required for one skilled in the art to practice the invention on any living creature other than avian.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-13, 15, 16, and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Wakenell et al.

The claims are drawn to a process for protecting a maternal-antibody-positive chicken embryo by administering an immunogenically effective amount of a vaccine comprising a live avirulent strain of infectious bronchitis virus (IBV) *in ovo* at approximately day 18 of incubation. The chicken embryos originate from a commercial stock of broilers. The vaccine protects the chickens from the pathological effects of virulent virus IBV upon exposure and does not significantly decrease the percentage of in ovo vaccinated chicken eggs that hatch upon the expiration of the incubation period.

Wakenell et al. teaches a commercial IBV vaccine (P₄₀-IBV) that was passaged in chicken kidney cell cultures to reduce the pathogenicity to become apathogenic for chicken embryos. Wakenell et al. carefully monitored the cell culture passages to insure that a desired level of infectivity did not diminish, see the discussion section on page 937. The strain was injected into chicken embryos at embryonation day 18. Maternal-antibody-positive chicks

Art Unit: 1648

hatching from eggs injected with P₄₀-IBV developed antibodies to IBV and were protected against challenge upon exposure to virulent Massachusetts strain 41 IBV at 4 weeks of age. See the abstract, materials and methods section on pages 933-934, "Protection against C-IBV" on page 934, "Comparative protective efficacy..." bridging pages 935-936, tables 2, 3, and 5, and the discussion section. In addition, Wakenell et al. teaches that the survival of chicks, i.e. hatchability, improved with increasing levels, see the "Effect of serial tissue culture passages..." bridging pages 934-935, tables 1 and 4 and the discussion section. The teachings of Wakenell et al. clearly anticipate the claims 1, 7-10, 12, 13, and 16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6, 14, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakenell et al.

The claims differ from the above claims in that they specify the amount of live virus, in EID50 units. Wakenell et al. uses a different unit to measure the amount of virus, and it is not clear how the reference PFUs convert to applicant's EID50 units. However, in the live vaccine art, it is a matter of routine to optimize dosages for optimum protection. The claimed ranges are seen as the result of routine optimization and therefore as *prima facie* obvious over the reference, absent unexpected results.

Art Unit: 1648

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 7:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
April 13, 2001

Mary Mosher

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800

160